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Nutritional Labeling of Food Products

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Milk
HOMOGENIZED
VITAMIN D
NUTRITION INFORMATION
(per serving)
Serving size = 1 cup
Servings per container = 4
CALORIES 160
PROTEIN . . . . . 9 grams
CARBOHYDRATE . . 12 grams
FAT . . . . . 9 grams
PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S.RDA)
PROTEIN 20
VITAMIN A 8
VITAMIN C 2
THIAMINE 4
RIBOFLAVIN 25
NIACIN . . . . . *
CALCIUM 30
IRON . . . . . *
VITAMIN D 25
PHOSPHORUS 20
*Contains less than 2 percent U.S.RDA of these nutrients.
Muffin Mix
NUTRITION INFORMATION
(per serving)
Serving size = 1 muffin
Servings per container = 12
Mix and 1 Egg and ½ cup Milk
CALORIES . . . . . Mix 120 130
PROTEIN (grams) 2 3
CARBOHYDRATE (grams) . . . 20 20
FAT (grams) 3 4
PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S.RDA)
PROTEIN 2 4
VITAMIN A . . . . . * 2
VITAMIN C . . . . . * *
THIAMINE 4 4
RIBOFLAVIN 2 4
NIACIN 2 2
CALCIUM 3 10
IRON 2 4
*Contains less than 2 percent U.S.RDA of Vitamin A and Vitamin C.
Dressing
NUTRITION INFORMATION
(per serving)
Serving size = 4 ounces
Servings per container = 4
CALORIES 440
PROTEIN . . . . . 15 grams
CARBOHYDRATE . . . . . 40 grams
FAT (percent of calories 51) . . . . . 25 grams
POLYUNSATURATED* . . . . . 5 grams
SATURATED . . . . . 10 grams
CHOLESTEROL* (30 mg/100 gms) . . . 35 mg.
SODIUM (200 mgms per 100 gms) . . . 230 mg.
PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S.R.D.A.)
PROTEIN 30
VITAMIN A 30
VITAMIN C 8
THIAMINE 15
RIBOFLAVIN 15
NIACIN 20
CALCIUM 2
IRON 8
* Information on fat and cholesterol content is provided for individuals who, on the advice of a physician, are modifying their total dietary intake of fat and cholesterol.

Preface

The information presented in this special report is a narrative condensation of extensive food labeling regulations issued by the Federal Food and Drug Administration (FDA) during 1973. It is paraphrased or re-worded and also considerably rearranged to provide a logical, readable sequence of information segments — more than was possible in the published regulations. Every effort has been made to describe accurately the original intent and meaning of the regulations, while at the same time culling them of the jargon characteristic of legal documents. By their very nature, however, regulations are subject to modification and amendment. The material discussed in this special report reflects the legal status as of the date of publication, although the general format and basic considerations in nutritional labeling, labeling of special-dietary-use foods and imitations are expected to remain essentially intact.

The author recognizes that large food processing firms may well be able to afford the time and money needed to interpret the regulations and to comply with suitable data gathering techniques. Moreover, a number of trade associations are in the process of gathering nutritional data on a variety of conventional food products. These data, once collected, will be made available nationwide to the food industry, small and large segments alike. This special report is primarily intended for the small processor unserved by trade association or educational council as well as the processor of specialty food products for whom data gathering services will be unavailable.

One other issue should not be overlooked. The FDA is committed to the philosophy that nutritional labeling should not impose an insuperable financial burden on the small food processor: the small firm should not be forced out of business because it is forced to assume excessively burdensome laboratory expenses in an effort to comply with these regulations. With this philosophy, the author heartily concurs. However, processors are still responsible for establishing and maintaining their own products in compliance and should apply quality control techniques adequate to the task. Besides obtaining reasonably precise composite nutrient data initially, nutrient levels will have to be monitored thereafter, and each food product poses its own unique quality control problem. Even in firms fortunate enough to have nutrient data provided by an outside agency, minor alterations in formulation or processing technique could result in significant changes in nutrient levels in violation of the regulations. Thus, while the information presented in this publication may help the processor understand and comply with nutritional labeling regulations, it cannot serve as a substitute for the regulations published in the Federal Register. In the final analysis, it is the processor who has the sole responsibility of meeting the letter and intent of the law.

Nutritional Labeling of Food Products

On January 19, 1973, the Food and Drug Administration published comprehensive proposals for labeling food products with specific nutritional information and for other broad changes in labeling regulations. Time for comment was allowed and a number of modifications introduced via the Federal Registers of March 14 and August 2, 1973. Together, these documents comprise the core of present-day food labeling regulations.

In a nutshell, food and nutritional labeling regulations do the following:

- Standardize the location of nutritional information on packages.
- Determine the kind of nutritional information that must appear on the label, how this information is derived, and its format.
- Define nutritional guidelines for classifying foods as imitation or nonimitation.
- Allow for spices, flavorings, and color to be declared categorically rather than singly.
- Define such terms as spice and natural and artificial flavoring.
- Define and spell out labeling requirements for special dietary foods.
- Define and establish labeling statements for dietary supplements of vitamins and minerals.

Mandatory Aspects of the Regulations

Nutritional labeling has been termed a "voluntary" program. There are, however, certain actions which automatically trigger the regulations. Nutritional labeling then becomes mandatory and full labeling is required.

The following actions compel nutritional labeling: (1) *the addition of vitamin, mineral, or protein to a food product* (examples are fortified nonfat dry milk, skim milk with added vitamins A and D, fruit drinks fortified with vitamin C) and/or (2) *the making of any nutritional*

claim, whether on the package or label or in media advertising. Mention of any nutrient or nutrient property, specifically vitamin, mineral, protein, carbohydrate, fat, fatty acids, cholesterol, calories or other nutrient factors, or even the use of such statements as "this food is nutritious," would demand nutritional labeling. The terms low fat on a milk carton, or low cholesterol on a container of salad dressing are examples of advertising that would initiate the regulations.

Some Exceptions Allowed

There are a few exceptions in which statements or advertising claims can be made without need for nutritional labeling.

1. Trade associations can make industry-wide nutritional claims — but only of nonbrand items. No reference can be made to specific brands, nor can a food processor refer to or use nutrition-related promotional material prepared by the trade association without complying with labeling regulations.

2. A company can reply with specific nutritional information to solicited or unsolicited consumer requests for such information. Or it can state on the container (or in advertising), "For nutrition information write to_____" and fill the blank with a company address — IF no other nutrition claim is made and IF the reply conforms to nutritional labeling regulations and IF no vitamin, mineral or protein is added to the food.

3. A company can provide professionals (physicians, dietitians, educators) with nutritional information directly, but must include or attach the nutritional information that the regulations require.

Other Exemptions

There are other exemptions which the regulations allow, although with provisos in certain instances. Some of these follow:

- The listing of sodium content.
- The listing of iodized salt (when otherwise properly labeled and listed in the ingredient section as *iodized salt* without further reference to the iodine or the salt on the label or in advertising).
- The addition of nutrient(s) solely for technological purposes (to be declared solely in the ingredient statement without further reference on the label or in advertising).
- The use of a standardized food containing added nutrient(s) (i.e., enriched flour, vitamin fortified nonfat dry milk) as a component in another food. Such products can be listed in the ingredients statement, but without further label or advertising reference.
- The shipment, in bulk, of food products intended for use solely in other foods and not for distribution to consumers in bulk form.
- Food products supplied for institutional use *only*. These foods may contain added vitamin, mineral or protein, or nutritional claims may be made about them, but only if current nutritional labeling information is supplied directly to the institution.

Foods Exempted Because Other Regulations Apply

Certain foods will not have to comply with the nutritional labeling regulation per se because other regulations cover them. Among these are: dietary supplements which are not marketed in food form, foods that may be the sole item in the diet, and foods used exclusively under medical supervision.

Some Claims Are Taboo

Certain advertising claims are banned altogether. Other claims will perhaps be allowed, but only when backed by scientific proof and only on approval by the FDA Commissioner.

Don't claim the following:

1. A product, because of presence or absence of certain dietary properties is useful in preventing or curing diseases or symptoms of disease.

2. A balanced diet of *ordinary* foods cannot supply adequate amounts of nutrition.

3. The soil on which the product is grown, is or may be the cause of inadequacies in the nutritive quality of the daily diet.

4. Storage, transportation, processing, or cooking of a food will or may cause an inadequacy in the quality of the daily diet.

5. A food has dietary properties when such properties are of no significant value or need in human nutrition. Ingredients not considered nutritionally significant at present are: rutin, other bioflavonoids, para-amino benzoic acid, inositol, and other similar substances.

6. A natural vitamin in a food is superior to an added vitamin. (Don't differentiate in any way between vitamins present naturally and those added.)

Certain Claims Must Be Validated

It is appropriate to claim that a food product is a "significant" source of a nutrient, but *only if that nutrient is present in the food at a level equal to or greater than 10 percent of the U. S. Recommended Daily Allowance (U. S. RDA) in a serving.*

It is appropriate to claim that a food is nutritionally "superior" to another food *only if it contains 10 percent more of the U. S. RDA* of the claimed nutrient per serving.

An example follows:

For Vitamin A, the U. S. RDA = 5,000 International Units (I. U.) (10 percent of 5,000 = 500). If Brand A contains 1,000 I. U. per serving (20 percent U. S. RDA) then Brand B, to claim nutritional superiority, must contain 1,000 + 500, or 1,500 I. U. per serving (30 percent U. S. RDA).

The Container, Itself

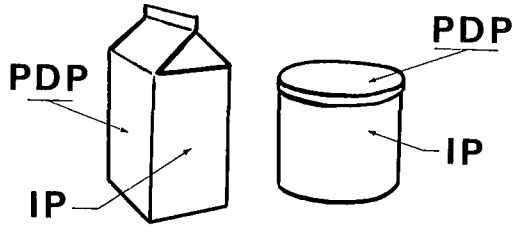
For determining where nutritional information will appear on the label, two terms must be defined. The first is *Principal Display Panel* (PDP). The PDP is that part of the container used specifically for identifying the product, i.e., that panel to which the customer looks for product identification. It may be the "front" of a rectangular container, or the top of a round container. Some containers may have more than one PDP.

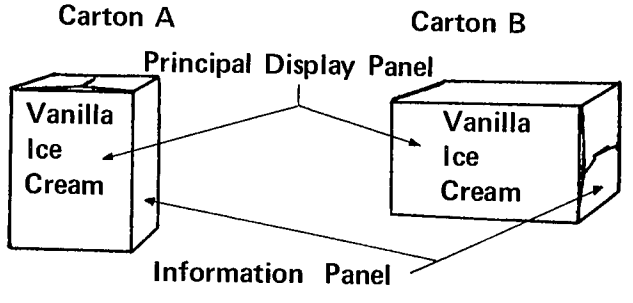
The second term is *Information Panel* (IP). This is the panel on which nutritional labeling information will normally appear. By FDA definition the Information Panel is that part of the package "immediately contiguous and to the right of the PDP as observed by an individual facing the PDP." (See illustrations.) Exceptions follow:

1. If the IP, as defined here, is too small to accommodate the necessary information or is otherwise unusable space (folded flaps or can ends), then the next contiguous panel to the right becomes the IP.

2. Where one or more alternate PDP's are present, the IP becomes the contiguous area to the right of any PDP.

3. If the top of the container is the PDP and there is no alternate PDP, the IP becomes any panel adjacent to the PDP.





Because packing methods vary and indeed must vary at times to accommodate unique food items, special labeling problems exist. Labeling regulations recognize — and account for — the more common of these problems.

PRODUCTS WITH SEPARATELY PACKAGED INGREDIENTS

If two or more ingredients are separately packaged and enclosed in an outer container, nutritional labeling of the total product must appear on the outer container.

If two or more products are simply combined (containers stuck or taped together and/or overwrapped with clear plastic) each product must bear separate nutritional labeling.

LABELING OF PRODUCTS COMMONLY COMBINED WITH OTHER INGREDIENT(S) PRIOR TO EATING

When one food product is ordinarily combined with another prior to eating (examples could be dry cereal and milk, or dry cake mix and finished cake) and directions for such combination are provided, a second column of figures may be included on the label showing the nutrient content of the final combination (see example inside front cover).

Size of Letters or Type

Information placed on either the Principal Display Panel or Information Panel must be prominent and conspicuous.

Unless special exemption is granted, *minimum letter and/or number size is 1/16 inch in height.*

All information required on either the PDP or IP should appear on the same panel. The only exception is insufficient space, then the information may be divided, but only in a specified manner.

If ingredient listing is required on the PDP, all other information, as specified by labeling laws, has to appear on the IP. Nutritional labeling information must appear in one place, undivided by intervening material.

If Your Label is Too Small

If a small label is your problem, petition the Commissioner of Food and Drugs for an alternative labeling method. This might include the following: smaller type, attached labeling, inserted labeling, or point of purchase distribution of label information. Already, proposals are pending which would allow smaller type size in certain situations.

Label Information

Nutritional labeling regulations not only tell the processor where to place the label information on the container and what size lettering to use, but determine (1) the specific information to be applied, (2) the order of listing, (3) increments allowed, (4) wording to be used, and (5) the official method(s) for obtaining the required analytical data.

For labeling purposes, foods can be classified by type of user and by amount of *added* vitamin and/or mineral present. Generally speaking labeling regulations recognize the following users:

- Infants (12 months and younger).
- Children under age 4.
- Adults and children age 4 or older.
- Persons with special dietary needs (pregnancy, lactation, diabetes, etc.).

When single or multiple vitamins and/or minerals are added to foods at such levels that the food attains or exceeds 50 percent of the U.S. Recommended Daily Allowance (U.S. RDA) of the vitamin(s) and/or mineral(s), it is considered as serving a "special dietary need." However, the declaration of nutritional information (specifically and solely) is required to conform with that of conventional foods with less than 50 percent added vitamin(s) and/or mineral(s) per serving.

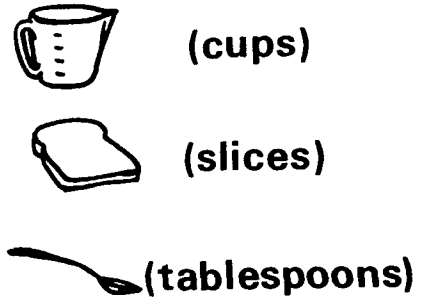
UNIT OF MEASUREMENT

Nutrient quantities must be declared in terms of an average or usual "serving" (or "portion" if the food is not ordinarily consumed directly). When reliable data have been established showing that the food is usually consumed more than once daily, and at average levels thus established, a second column of figures may be presented (by the standard format) expressing nutritional information on a *daily* basis.

A "serving" is designated as that reasonable amount of food consumed by (a) an adult male engaged in light physical activity or (b) an infant or child under age 4 (for foods marketed for this age group).

"Portion" refers to that amount of food ordinarily used in the preparation of a meal component when used *only* as an ingredient.

The preceding quantities must be expressed on the basis of the food *as packaged.* Another column of figures may be used to declare nutrient quantities as consumed *after cooking or other preparation,* providing the cooking or preparation method is clearly disclosed. Cooking or preparation method should follow immediately the nutritional declaration information on the label.



ORDER OF LISTING NUTRITIONAL INFORMATION

The standardized format for listing nutritional information follows. Nutrient data, headings used and order of listing, are specified in the regulations (see examples inside front cover).

Nutritional data must appear headed by the words "Nutritional Information." The words "per serving" or "per portion" are optional in the heading. But, if used, these words may either follow or be placed under the heading "Nutritional Information." The following information and format is required:

- Serving (portion) size — (cup, wafer, slice, etc.).
- Serving (portions) per container.
- Caloric content[1] (or "Calories") per serving (portion) expressed to the nearest: 2 calorie increment up to and including 20 calories, 5 calorie increment up to and including 50 calories, 10 calorie increment above 50 calories.
- Protein content[2] (or Protein) — the number of grams of protein per serving (portion) expressed to the nearest gram.
- Carbohydrate content (or Carbohydrate) — the number of grams of carbohydrate per serving (portion) expressed to the nearest gram.
- Fat content (or Fat) — the number of grams of fat per serving (portion) expressed to the nearest gram.

Fatty acid composition, cholesterol, and sodium content may also be declared. The required label information for fatty acid composition and/or cholesterol should immediately follow the fat content statement. A declaratory statement is also required and may follow (singly or combined) or be referenced and placed directly following the completed nutritional information statement. When fatty acid composition is provided, cholesterol content, if given, should follow the composition statement on fatty acids.

Required information on sodium content, if declared, should follow the statement on fat content (or fatty acid and/or cholesterol, if stated).

Immediately following the statement of fat content (or fatty acid, cholesterol or sodium content, if listed) certain additional nutrient data must appear. The heading for this section is entitled, "Percentage of U.S. Recommended Daily Allowances (U. S. RDA)." Under this heading is a statement of the amount per serving (portion) of protein and certain designated vitamins and minerals.

Increments for expressing these values follow:

2% — up to and including the 10-percent level.

5% — above the 10-percent level and up to and including the 50-percent level.

10% — above the 50-percent level.

Nutrients present in amounts of less than 2 percent U. S. RDA may be designated by a zero or an asterisk directing the reader to a statement at the bottom of the table, which reads "contains less than 2 percent of the U. S. RDA of this (these) nutrient(s)."

[1] The Atwater method described in USDA Handbook 74 (1955) is required for calorie analyses. Or, caloric content may be calculated on the bases of 4, 4, and 9 calories per gram for protein, carbohydrate, and fat, respectively *UNLESS* the determined values are above 20 percent of those obtained by the Atwater method.

[2] Protein may be calculated on the basis of the factor 6.25 times the nitrogen content as determined by the appropriate Association of Official Analytical Chemists (11th edition) method, *except* when the official procedure for a specific food requires another factor.

If a product contains less than 2 percent of the U. S. RDA for each of *five or more of the 8 nutrients specified,* this fact, if desired, may be indicated by listing no more than 3 of those nutrients, with the statement "contains less than 2 percent of the U. S. RDA of_____," listing those nutrients not otherwise declared.

The order of listing nutrients cannot vary. This order, and the nutrients that must be declared (unless subject to the provision in the preceding paragraph) follow: Protein, Vitamin A, Vitamin C, Thiamine, Riboflavin, Niacin, Calcium, and Iron.

At all times, this listed nutrient content must be expressed as percent of U. S. RDA per serving (portion).

When other vitamins and/or minerals are *added,* including vitamin D, vitamin E, vitamin B_6, folic acid, vitamin B_{12}, phosphorus, iodine, magnesium, zinc, copper, biotin, and pantothenic acid, these *must* be declared also as a percent of U. S. RDA per serving (portion) and in the listed order. If such nutrients are present naturally, this listing is optional. If declared, the listed order must be used.

The U. S. RDA and appropriate nomenclature for each of these nutrients follow.

U. S. Recommended Daily Allowances (RDA) Established for Nutrients Considered in Nutritional Labeling

Nutrient[3]	U. S. RDA	Nutrient[3]	U. S. RDA
Vitamin A	5,000 International Units	Folic acid	0.4 milligram
Vitamin C	60 milligrams	Vitamin B_{12}	6.0 micrograms
Thiamine	1.5 milligrams	Phosphorus	1.0 gram
Riboflavin	1.7 milligrams	Iodine	150 micrograms
Niacin	20 milligrams	Magnesium	400 milligrams
Calcium	1.0 gram	Zinc	15 milligrams
Iron	18 milligrams	Copper	2 milligrams
Vitamin D	400 International Units	Biotin	0.3 milligram
Vitamin E	30 International Units	Pantothenic Acid	10 milligrams
Vitamin B_6	2.0 milligrams		

For children over age 4 and for adults the percentage nutrients per serving (or portion) for any given food product will be based on these U. S. RDA's. Where applicable, food marketed solely for infants must present percentages based on infant needs (page 11).

A few synonyms are allowed and may be added in parentheses immediately following Biotin 0.3 milligrams. These are:

Vitamin C — ascorbic acid
Riboflavin — Vitamin B_2
Thiamine — Vitamin B_1

On March 6, 1974, FDA published two further proposals for nutritional labeling of food products. While these are proposals, not finalized regulations, a summary of these documents seems worthwhile.

Foods That Contain Less Then One Gram of Protein, Fat, or Carbohydrate

The original regulation provided for label declaration of protein, carbohydrate, and fat content only to the nearest gram per serving. Foods with less than one-half gram per serving could not be labeled to express that fact. With a concurrent proposal for labeling products which are not meaningful sources of nutrients, FDA now proposes to allow declaration of protein, carbohydrate and/or fat content of foods when these nutrients are in fact present, though in quantities of less than one gram per serving. This will be done by means of the phrase "Contains less than one gram," placed after the appropriate nutrient.

Foods That Are Not Meaningful Sources of Nutrients

This amendment would allow alternatives for the nutritional labeling of foods that (1) provide less than 25 calories and 2 percent U. S. RDA per serving of protein and of each of the seven designated vitamins and minerals and (2) supply calories derived from one component only (protein or carbohydrate or fat). The former is designed to accommodate low or no-calorie foods, the latter for products such as sugar. Labeling is handled in the following manner:

In lieu of "Protein Content," "Carbohydrate Content," and "Fat Content," the alternatives are, where appropriate:

For category (1):
- a) "Contains less than 1 gram each of protein, carbohydrate and fat"
- b) "Contains no protein, fat, or carbohydrate"

For category (2):
- c) "Contains no _____", the blank being filled in with the appropriate missing nutrients (protein, fat, or carbohydrate).

In lieu of "Percentage of U. S. Recommended Dietary Allowances (U. S. RDA)" the alternatives are, where appropriate:

[3] These nutrients and levels were derived by the FDA from "Recommended Dietary Allowances" published by the Food and Nutrition Board, National Academy of Sciences — National Research Council. They are subject to change as more nutritional information becomes available.

For category (1):

a) "Contains less than two percent of the U. S. RDA of any vitamins or minerals" (when, in fact, the product does contain some vitamin or mineral, but in quantities less than two percent)

b) "Contains no vitamins or minerals"

For category (2):

c) "Contains less than two percent of the U.S. RDA of any vitamin or mineral" (when this is a true statement, and some vitamin and mineral is in fact present)

d) "Contains no _____ and no vitamins or minerals," the blank being filled in with the words protein or carbohydrate or fat, whichever is appropriate. In this case the two declarations—the one for protein, carbohydrate, and fat content and also the one for vitamin and mineral content—may be combined as indicated.

Protein Quality and U. S. RDA

Protein is different from other nutrients because it varies in quality. Some proteins, for any given amount consumed, supply more of the essential growth and body repair factors than others. For the person interested in evaluating food products for protein content, both quantity *and* quality should be considered.

There are several methods of evaluating protein quality. Different methods sometimes evaluate slightly different nutritive factors. Researchers are not in total agreement concerning which test and/or factor provides the best assessment of protein quality. However, for nutritional labeling, FDA selected Protein Efficiency Ratio (PER) as the measure of quality to be applied in compliance with the law. PER is defined as weight gain divided by protein consumed for test rats after 4 weeks of feeding trials using test protein and a casein-based diet. Casein is the major protein component of cow's milk and has a PER of 2.5. If another protein were found to have a PER 40 percent that of casein, it would be reported as 0.40 x 2.5 = *1.0 PER*.

One criticism sometimes leveled against PER is that it measures growth (weight gain) only. Proteins have an additional bodily function, that of maintenance, and some proteins with relatively low PER may have significant maintenance value.

In nutritional labeling, the U. S. RDA is considered to be 45 grams if the PER of the protein in the product is equal to or greater than that of casein. If the PER is less than casein, the U. S. RDA becomes 65 grams. However, if the protein has a PER less than 20 percent the PER of casein, then it cannot be declared in terms of percentage U. S. RDA. Rather, the statements on protein content in grams per serving must read: "not a significant source of protein." This statement must be used irrespective of the actual amount of protein present.

For infants and children under age 4, the U. S. RDA protein values are, respectively, 20 and 28 grams, with the preceding qualifications.

Calculating Percentage U. S. RDA of Protein

Let's suppose you've analyzed the protein content of a food product which provides 15 grams of protein per serving; the PER has been determined to be 3, higher than casein. Since the PER is above that of casein, you will use 45 grams as the U. S. RDA.

Then: $15 \div 45 = .33 \times 100 = 33$ percent U. S. RDA

Or assume that the protein is inferior to casein in PER, let's say 2.0 PER. Then, if the product contained 13 grams of protein the calculation would be:

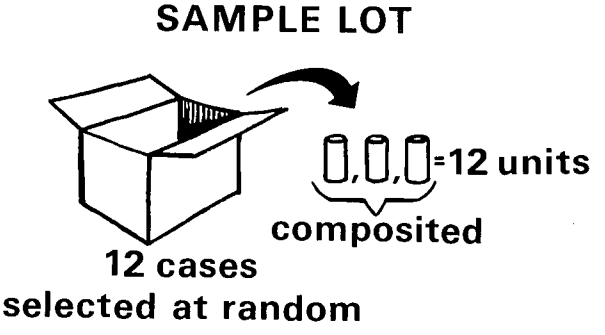
$13 \div 65 = .20 \times 100 = 20$ percent U. S. RDA

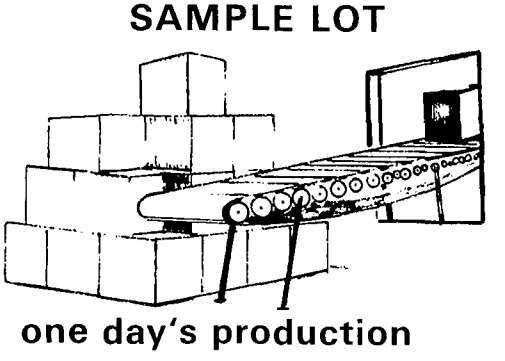
The only change is in the substitution of 65 grams as the U. S. RDA in place of 45 grams.

The Analysis of Nutrients

THE SAMPLE

The sample used for analysis of nutrients is as important as the procedure used to analyze that sample. Of necessity, a sample must represent — as nearly as possible — the total production. For purposes of nutritional labeling, a sample "lot" is defined as (1) a collection of primary containers or units of the same *size, type,* and *style* produced under conditions as nearly uniform as possible or (2) a day's production (to be used in the absence of any common container code or marking). Pasteurized milk is a product that falls under category (2): a product that is processed continuously throughout the day.





'LOT' SIZE AND SELECTION

The sample which is used for nutrient analysis (if not one day's production) must be a composite of 12 consumer units. Select one unit from each of 12 different shipping cases selected at random. A well mixed composite of these 12 units then constitutes a sample "lot."

METHODS OF ANALYSIS

Composite samples must be analyzed by Association of Official Analytical Chemists (AOAC) methods (when available). If no AOAC method is available, other appropriate, reliable procedures can be used. Or, alternative methods may be used upon petition to, and approval by, the FDA.

CLASSIFICATION OF NUTRIENTS (For Compliance Purposes)

Nutrients in food products are either present naturally or are added intentionally for purposes of fortification. Skim milk with added vitamins A and D is an example of a "fortified" product. While the quality (nutritive value) of added and natural nutrients is considered equivalent, the content of naturally occurring nutrients tends to vary more widely than does the content of added nutrients, the latter of which are subject only to processing variability. Therefore, for compliance purposes, nutrients are classified:

Class I — nutrients added in fortified or fabricated products.

Class II — nutrients occurring naturally.

The regulations take into account the variability of nutrient levels stemming from these two sources: Class I vitamin, mineral, or protein must be present in the composite sample at a level at least *equal to* the amount declared on the label; Class II vitamin, mineral, or protein must be present in the composite sample to at least *80 percent* of the nutrient value declared on the label.

When an ingredient containing Class II nutrients is added to a food, the total amount of Class II nutrients in the finished food becomes the level subject to requirements for this group of compounds.

Limitations are also placed on overages of calories, carbohydrates, and fat, and also for fatty acids and cholesterol, when declared. The composite sample must never contain more than *20 percent* in excess of the declared amount.

OVERAGES AND UNDERAGES

The food processor should keep in mind that there are several sources of variability in the amount of nutrient as determined analytically in any product. Not only are there natural and/or processing variables, but composite samples and test procedures per se are potential sources of variations.[4]

For compliance purposes the FDA allows underages of Class I and II nutrients only by a factor less than the variability of the test method itself at the *specific level of testing involved.* In other words testing error is recognized and is provided for, but variations among composite samples will have to be accounted for by the processor; that is, the processor should determine a standard deviation for lot differences and declare an amount of nutrient 3 standard deviations below the average value for Class I nutrients and 3 standard deviations below 80 percent of the average value for Class II nutrients to assure compliance.

Reasonable deficiencies of calories or fat are allowed *within good manufacturing practices.* But again, composite variability must be considered and the product labeled accordingly lower.

Reasonable excesses of vitamin, mineral, or protein over labeled amounts are acceptable *within good manufacturing practices.*

FAT, FATTY ACID, AND CHOLESTEROL LABELING

No advertising claims can be made regarding fat, fatty acid, or cholesterol level (or property) of a food without providing nutritional labeling. Specific label requirements have been established for this nutrient category.

In chemist's terms, fats are called triglycerides: meaning they are made up of glycerol and three fatty acids. Properties of fats vary depending on the length of the fatty acid chain, the position of the fatty acid (where more than one kind is a part of the molecule) on the glycerol molecule, and the saturation or unsaturation of the fatty acid. Saturation refers to the way in which parts of a fatty acid are joined together. Saturated fats (hard fats) are those in which the fatty acid parts (atoms) are linked together by single bonds. In unsaturated fats (soft fats) double bonds occur.

Cholesterol, as the name implies, is, chemically speaking, a sterol. It is found naturally occurring in blood and in a number of animal tissues and organs.

Although the definitions here are specifically of fat, fatty acid, and cholesterol labeling requirements, whenever nutritional labeling is indicated, the total package of nutrient information, as covered previously, must be included on the label. Also, exact placement on the label is specified. (See LABEL INFORMATION section for a discussion of nutrient information required and label location for fat, fatty acid, and cholesterol information.)

Cholesterol Labeling

When labeling cholesterol content, express cholesterol levels both to (1) the nearest 5 milligram increment per serving and (2) the nearest 5 milligram increment per 100 grams of the food product. Also include the declaratory statement indicated under "Fatty Acid Labeling."

Restrictions on Fatty Acid Labeling

Fatty acid information may be included on the label only if the food contains 10 percent or more fat on a dry basis and not less than 2 grams of fat per average serving.

[4] For a discussion of FDA compliance procedures, obtain a copy of "Compliance Procedures for Nutritional Labeling," Division of Mathematics, Food and Drug Administration, 200 C Street S. W., Washington, D. C. 20204.

Anything less is considered unsuitable in regulating intake of fatty acids.

Fatty Acid Labeling

Information required on the label for fatty acid labeling calls for the following:

- Total fat content — as percent of total calories in the food, under the heading: "Percent of calories from fat."

- Unsaturated fatty acids — calculated as trigylcerides and stated in grams/serving to the nearest gram. These are to be stated as "Polyunsaturated" and include cis, cis-methylene interrupted polyunsaturated fatty acids.

- Saturated fatty acids — calculated as triglycerides and stated in grams/serving to the nearest gram. These are to be listed as "Saturated" and must include the sum of lauric, myristic, palmitic, and stearic acids.

- The statement: "Information on fat (and/or cholesterol, where appropriate) content is provided for individuals who, on the advice of a physician, are modifying their total dietary intake of fat (and/or cholesterol, where appropriate)."

If desired, the following statement can be placed on the Principal Display Panel: "Cholesterol information appears ————," with directions for finding same. Type size is limited to 1/16 inch (or no larger than one-half the minimum type size required for declaration of net quantity of contents). See inside front cover for an illustration of fat, fatty acid, and cholesterol labeling.

Overages and Underages

As indicated before, overages of fat, fatty acids, and cholesterol may not exceed 20 percent (in the composite sample) of the declared value. If you declare 50 calories, then the caloric content should not exceed 50 x 1.20 = 60 calories. Or if you label 10 grams of fat, then the composit sample should not exceed 12 grams of fat (10 x 1.20 = 12 grams).

USDA Proposals

As regulatory authority for the meat industry, the U. S. Department of Agriculture, on January 11, 1974, issued proposals for the nutritional labeling of meat and poultry products. If finalized as proposed, few differences will exist between USDA and FDA regulations. Mandatory labeling will be required when nutrients are added or nutrition advertised; nutrient declaration and format for listing nutrients remains nearly the same.

Of those changes that are being proposed, the ones that appear to be of most significance to the processor follow:

- With minor exceptions, the PDP of a cylindrical container would be 40 percent of the circumference (0.40 x [height x circumference]), of any other container 40 percent of the total surface (except where an obvious PDP exists, such as the top of a triangular or circular package, in which case the PDP becomes the entire surface). Rules for selecting the IP are about the same as FDA rules.

- Serving size must be expressed in common units — one or two links of sausage; a slice of meat, half a container of chili (where there are two servings per container), etc.

- If the product requires cooking prior to eating, two columns of nutrient values *must* be displayed, one showing nutrient content before cooking, the other after cooking. *And* — the directions for cooking must immediately follow the nutrient declaration.

- Compliance calls for (1) a plant quality control system adequate to the task (one that provides a "high degree of assurance" that products meet labeling claims), (2) a written description of methods used to maintain uniformity of raw ingredients and, where applicable, disclosure to USDA of product formulation, handling, and processing methods, (3) a "lot" for analyses made up of 12 randomly selected "immediate" containers, and (4) maintenance of the quality control program by the plant and verification by either the plant or its agent of appropriate control. Verification consists of the analysis of "12 individual randomly selected immediate containers from lots of that product processed at the establishment during the first year labeling is approved." Either AOAC or other "approved" methods are required, and results must be correlated with label claims. Revision of the sampling requirements after the first year will be published at a later date.

SPECIAL DIETARY FOODS

Prior to the FDA proposals of January 19, 1973, a number of vitamin and/or mineral fortified foods were categorized for food labeling purposes as "Special Dietary Foods." The new regulations recognize that some of these foods, such as vitamin/mineral-fortified nonfat dry milk, are traditional foods for general consumption. As such, they are now regulated under §1.17 of the nutritional labeling regulations. The Special Dietary Foods category still exists, but is limited to (1) foods that truly serve a special dietary need, (2) foods represented for use as the sole item of the daily diet, and (3) dietary supplements.

Category (1) includes such conditions as convalescence, pregnancy, lactation, infancy (under 12 months of age), allergic hypersensitivity to food, underweight condition, diabetes mellitus, or the need to control the intake of sodium.

The use of an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food which cannot be achieved with sugar or other nutritive sweetener, is considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics. Such foods are, therefore, considered Special Dietary Foods.

Establishing U. S. RDA's

The method used to determine reasonable U. S. RDA values for each dietary need category was to select the highest value for each group. In this way it was assumed all individual needs would be met. Some, of course, would be exceeded, but this should not endanger health.

Table 1. Nutrients, U. S. RDA, and Order of Listing Nutrients for "special dietary use" foods

Vitamins[1] and minerals	Units of measurement	Infants	Children under age 4	Upper limit	Adults and children age 4 or older	Upper limit	Pregnant or lactating women	Upper limit
Vitamin A	International units	1,500	2,500	(2,500)	5,000	(5,000)	8,000	(8,000)
Vitamin D	do	400	400	(400)	400	(——)	400	(400)
Vitamin E	do	5	10	(15)	30	(45)	30	(60)
Vitamin C	Milligrams	35	40	(60)	60	(90)	60	(120)
Folic acid	do	0.1	0.2	(0.3)	0.4	(0.4)	0.8	(0.8)
Thiamine	do	0.5	0.7	(1.05)	1.5	(2.25)	1.7	(3.0)
Riboflavin	do	0.6	0.8	(1.2)	1.7	(2.6)	2.0	(3.4)
Niacin	do	8	9.0	(13.5)	20	(30.0)	20	(40)
Vitamin B_6	do	0.4	0.7	(1.05)	2.0	(3.0)	2.5	(4.0)
Vitamin B_{12}	Micrograms	2	3	(4.5)	6	(9.0)	8	(12.0)
Biotin	Milligrams	0.15	.15	(0.225)	0.3	(.45)	0.3	(0.6)
Panthothenic Acid	do	3	5.0	(7.5)	10	(15)	10	(20)
Calcium	Grams	0.6	0.8	(1.2)	1.0	(1.5)	1.3	(2.0)
Phosphorus	do	0.5	0.8	(1.2)	1.0	(1.5)	1.3	(——)
Iodine	Micrograms	45	70	(105)	150	(225)	150	(300)
Iron	Milligrams	15	10	(15)	18	(27)	18	(60)
Magnesium	do	70	200	(300)	400	(600)	450	(800)
Copper	do	0.6	1.0	(1.5)	2.0	(3.0)	2.0	(4.0)
Zinc	do	5	8.0	(12)	15	(22.5)	15	(30)

[1] The following synonyms may be added in parentheses immediately following the name of the vitamin:

Vitamin	Synonym
Vitamin C	Ascorbic acid
Folic acid	folacin
Riboflavin	vitamin B_2
Thiamine	vitamin B_1

Labeling of Foods for 'Special Dietary Use'

The nutrients, the U. S. RDA's, and the order of listing nutrients for "Special Dietary Use" foods are found in the above table.

In addition to those listed in table 1, other vitamins and minerals are recognized as essential to human nutrition, such as vitamin K, choline and the minerals chlorine, potassium, sodium, sulfur, fluorine, and manganese. U. S. RDA's have not been established for these nutrients, however, and they are not considered appropriate for addition to general purpose foods or dietary supplements of vitamins and minerals. They may be added to other foods, such as infant formulas or foods for use solely under medical supervision, to meet special dietary use needs.

When labeling a "Special Dietary Use" food, a statement regarding the usefulness and/or special dietary properties should be printed on the Principal Display Panel, if possible. If space is lacking, the Information Panel may be used. The statement should indicate the presence or absence of any substance, any alteration in the quantity or character of any constituent, and any special dietary property of the food.

The heading for nutrient listing of special dietary foods is:

"Percentage U. S. Recommended Daily Allowances." The order of listing in table 1 must be followed and values on the label should express percentages of the U. S. RDA indicated. When the food is for use by one or more of the groups for which U. S. RDA are established, the listing of nutrients should include the percentage for each age group. Percentages must be expressed to the nearest whole number, and the food quantity specified should be an amount suitable for consumption *within 1 day*.

Some Claims Cannot Be Made

As in nutritional labeling, certain claims are prohibited for special dietary foods.

Do *not claim* the following:

1. Products intended to supplement diets are sufficient in themselves to prevent, treat, or cure disease (with certain exceptions).

2. A balanced diet of ordinary foods cannot supply adequate nutrition.

3. A deficiency in the diet is due to the soil on which a food is grown.

4. Transportation, storage, or cooking of foods may result in inadequacy or deficiency in the quality of the daily diet.

5. Compounds such as rutin, other bioflavonoids, paraaminobenzoic acid, inositol, and similar products have nutritive value. *Do not combine such products with "essential" nutrients.* Products of this type may be marketed as individual products or in mixtures, but only in *absence* of label statements implying nutritional, dietary, or therapeutic value. Don't make statements to the effect that nutri-

tional usefulness of the product has not been established, or otherwise disclaim nutritional value.

6. A natural vitamin is superior to an added or synthetic vitamin.

Overages and Underages

The total amount of vitamins or minerals in the food must be no less than the amount declared and no more than a reasonable amount above the declared amount. Reasonable variations caused by heat, light, oxidation, storage, transportation, or unavoidable deviations in good manufacturing practices are recognized and permitted.

Exception

Iodized salt is exempt from this regulation when the declared content of iodine compound in the salt is *equivalent* to 0.01 percent by weight of iodine.

Distinguishing Between Food and Drugs

Thumb rules can be applied to help classify foods for labeling purposes.

- Use "nutritional labeling" on foods containing less than 50 percent U. S. RDA per serving of any one or more of the essential nutrients.
- Label as "dietary supplements" foods containing 50-150 percent of the U. S. RDA per serving of any one or more of the essential nutrients.
- Classify as drug any product that contains more than 150 percent of the U. S. RDA per serving of any one or more of the essential nutrients.

Table 1 indicates the top levels for "Special Dietary Use" foods. Above these levels, products must be classified as drugs.

The exceptions to the 150 percent rule are (1) nutrients known to have significant toxic properties or side effects, (2) conventional foods which contain naturally occurring nutrient amounts in excess of the 150 percent level, (3) foods to which nutrients are added to attain nutritional equivalency (to avoid the "imitation" status), (4) certain infant formulas, and (5) foods for use solely under medical supervision.

'IMITATION' FOODS

By definition, imitation denotes a copy of or substitute for genuine articles or goods. By implication, the word suggests inferiority. But what of the imitation food that is nutritionally the equal of its genuine counterpart? If the imitation satisfactorily meets all other quality attributes — flavor, texture, and appearance — and is also essentially as wholesome nutritionally, should it be required to bear the stigma of inferiority associated with the word imitation? Labeling regulations now say no, by defining nutritional equivalence. As long as the "essential nutrients" present in a traditional food at levels of 2 percent or more U. S. RDA per average serving are found in *equal amounts* in the substitute, it need not be labeled imitation. The "essential nutrient" list includes protein and the 19 vitamins and minerals in table 1. In other words, a food need not be labeled imitation unless it is nutritionally inferior.

Reductions in fat or caloric content will not constitute nutritional inferiority if the food is labeled according to nutritional labeling regulations and if caloric reductions do not violate "special dietary use" regulations.

Other Label Requirements for 'Substitute' Foods

The nutritionally equivalent substitute food must bear a common or usual name or, in absence of such, an appropriately descriptive term that is not false or misleading. It may also bear a fanciful name. However, it may not carry the name of the food it resembles.

Acknowledgment

While all information included in this report was derived directly from appropriate issues of the Federal Register, much help in gaining a perspective of the regulations came from reading current, informative copies of *Thrust,* a publication of the Milk Industry Foundation. The two illustrations showing various container panel locations were taken from publications of this association and insights gained were most helpful.

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